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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Kenji Sunagawa

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

PAPER NUMBER

3762

NOTIFICATION DATE

DELIVERY MODE

12/16/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/523,539	Applicant(s) SUNAGAWA ET AL.	
	Examiner MICHAEL KAHRELIN	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-12 and 19-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-12 and 19-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 7-12 and 19-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In regards to claim 7, it is unclear whether the claim requires the calculation of the "impulse response" by taking the "inverse Fourier transform of a transfer function which is based on a Fourier transform of normal-activity biosignals," or whether the system need only be capable of utilizing such an impulse response, however calculated. If applicant does not wish to positively recite this step, it is suggested to recite a "calculating means...adapted to calculate a plurality of stimulation signals." If Applicant wishes to recite this step, it is suggested to positively recite an element/method step in the active voice of, e.g., "calculating a transfer function by computing a Fourier transform of normal-activity biosignals from normal biologic activities; calculating an impulse response by computing an inverse Fourier transform of said transfer function..." As Applicant has indicated that the system does not necessarily compute the impulse response and the limitation is recited in the passive voice, the Examiner is considering the claim to NOT require the impulse response to be calculated from an inverse Fourier transform of a transfer function which is based on a Fourier transform of normal-activity biosignals, but only be capable of using such an impulse response. The clarity issue with these claims is not *what* the impulse response

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is, as this feature is described in the specification and is known in the art. The issue is whether Applicant is positively reciting that the impulse response must be calculated by performing steps corresponding to the claimed functional limitations. The Examiner's position is that the current claim language does not require this, as Applicant has indicated such in "Remarks" (see communication of 4/27/2009), but this is not adequately conveyed in the claim language because this feature is not clearly functionally recited. Further, the method step "a)" uses the passive voice, rendering it unclear whether the limitations after "impulse response" are required limitations.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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5. Claims 7-12 and 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shalev (US 2006/0089678, hereinafter "Shalev") in view of Constant (US 4,006,351, hereinafter "Constant").

6. In regards to claims 7 and 12, Shalev discloses the essential features of the claimed invention including a biological activity sensing means that senses biological activity and outputs a plurality of input biosignals (Fig. 2, element 20); a calculating means that receives the input biosignals, calculates a plurality of stimulation signals using the input signals, and outputs the stimulation signals for stimulation of the organism (element 24); and an organism stimulating means that receives the stimulation signals and stimulates the organism based on the signals (element 26), depending on whether the input biosignals are caused by normal or abnormal biological activities (pars. 0062 and 0063). Although Shalev discloses that the calculating means utilizes a transfer function based on previous responses obtained from normal biologic activity (par. 0062 and Fig. 1B), Shalev does not explicitly disclose that the stimulation signal is calculated from a convolution integral between an impulse response previously obtained and the input signals. However, Constant teaches a calculating means for applying transfer functions wherein the output signal is calculated from a convolution integral between an impulse response previously obtained and the input signals (abstract) to provide the predictable results of a better measurement of time delay and frequency relationships in a noisy environment (col. 5, lines 37-48). Therefore, it would have been obvious to one having ordinary skill in that art at the time the invention was made to modify Shalev's invention by providing a calculating means for applying the

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transfer function wherein the output signal is calculated from a convolution integral between an impulse response previously obtained and the input signal to provide the predictable results of a better measurement of time delay and frequency relationships in a noisy environment. Due to Applicant's position that the claims do not require that the system calculate the impulse response using a Fourier transform and inverse Fourier transform, the Examiner is of the position that Shalev's modified system is capable of calculating stimulation signals using a impulse response calculated in the way recited in the "wherein" clause of claim 7, or an impulse response calculated in any other way.

7. In regards to claims 8 and 9, the sensing means is a pressure sensor and the activity is blood pressure (element 20).

8. In regards to claim 10, the stimulating means is an electrical stimulating means (par. 0063).

9. In regards to claim 11, Shaley's modified invention discloses the essential features of the claimed invention including a signal conditioner (106), an A/D converter (108), and an analyzer (110), but does not explicitly disclose that the signal conditioner includes an amplifier. However, it is notorious in the electrical stimulation and arts to provide signal sensing means with amplifiers to provide the predictable results of maximizing the signal of interest and minimizing noise. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Shaley's invention by providing the signal sensing means with an amplifier to provide the predictable results of maximizing the signal of interest and minimizing noise.

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10. In regards to claims 19 and 20, Shalev discloses the essential features of the claimed invention including calculating at least one transfer function (pars. 0062 and 0063); sensing biological activity information issued by biological activities and outputting a plurality of input biosignals (Fig. 2, element 20); calculating a plurality of stimulation signals using the input signals and an impulse response (col. 4, lines 12-20), and outputting the stimulation signals for stimulation of the organism (element 24 and 26) depending on whether the input biosignals are caused by normal or abnormal biological activities (pars. 0062 and 0063). Although Shaley discloses calculating by utilizing a transfer function based on previous responses obtained from normal biologic activity (par. 0062 and Fig. 1B), Shaley does not explicitly disclose that the stimulation signal is calculated from a convolution integral between an impulse response previously obtained from an inverse Fourier transform of a transfer function and the input signals. However, Constant teaches a calculating means for applying transfer functions wherein the output signal is calculated from a convolution integral between an impulse response previously obtained from an inverse Fourier transform and the input signals (abstract and Fig. 1a) to provide the predictable results of a better measurement of time delay and frequency relationships in a noisy environment (col. 5, lines 37-48). Furthermore, it is well known in the signal processing arts to derive transfer functions (or impulse responses) and corresponding output signals in either the time (convolution integral) or frequency (Fourier transform) domains to provide the predictable results of effectively controlling systems with known filters and algorithms. Therefore, it would have been obvious to one having ordinary skill in that art at the time the invention was made to

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modify Shalev's invention by calculating the stimulation signal from a convolution integral between an impulse response previously obtained from an inverse Fourier transform of a transfer function and the input signals to provide the predictable results of a better measurement of time delay and frequency relationships in a noisy environment using known filters and algorithms. Due to Applicant's recitation in the passive voice of "based on a Fourier transform of normal activity biosignals from normal biological activities," the Examiner is of the position that this limitation is not a recited active method step.

11. In regards to claim 21, the stimulating means is an electrical stimulating means (par. 0063).

12. In regards to claims 22 and 23, the sensing means is a pressure sensor and the activity is blood pressure (element 20).

13. In regards to claim 24, Shaley's modified invention discloses the essential features of the claimed invention including a signal conditioner (106), an A/D converter (108), and an analyzer (110), but does not explicitly disclose that the signal conditioner includes an amplifier. However, it is notorious in the electrical stimulation and arts to provide signal sensing means with amplifiers to provide the predictable results of maximizing the signal of interest and minimizing noise. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Shaley's invention by providing the signal sensing means with an amplifier to provide the predictable results of maximizing the signal of interest and minimizing noise.

Response to Arguments

14. Applicant's arguments filed 9/30/2009 have been fully considered but they are not persuasive. The Examiner maintains the rejection of claims 7-12 and 19-24 under 35 U.S.C. § 112, paragraph 2, as indicated above. It is not unclear *what* the impulse response is, but rather whether the claim requires the impulse response to be calculated in the recited way. Although Applicant has indicated in remarks that the device/method need not calculate this parameter, the claim language still seems to recite this element. It is suggested to clearly functionally recite this element if positive recitation is not desired. For instance, claim 1 could read "a calculating means...adapted to calculate" to indicate that the calculating means need not actually calculate the impulse response as recited, but only be capable of using such an impulse response. If applicant wishes to require that the impulse response be calculated in the recited way, it is suggested to recite some element that "calculates a Fourier transform of normal-activity biosignals; calculates a transfer function based on said Fourier transform," etc.

15. Applicant argued that Constant's teachings cannot be applied to Shalev because Constant is drawn to linear time-invariant systems, while Shalev is drawn to a biological system having complicating variables such as hormones, body temperature, and oxygen concentration besides the input signals. However, it is these and other variables for which the linear transfer function disclosed by Shalev at paragraph 0062 is intended to account for. Although Constant may or may not disclose "biological responsiveness," Shalev discloses that the biological transfer function can be a linear

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function, and thus Constant's algorithm would be applicable to this function. Constant is merely one of many teachings of deriving a "black box" transfer function through Fourier transform. Furthermore, the Examiner respectfully disagrees that the teachings are not analogous because "biological responsiveness" in "different organs of the organism" is incapable of being characterized as a linear system. Not only is Shalev drawn to merely controlling the relationship between nerve firing rate and blood pressure (and not "all organs"), Shalev expressly discloses that this relationship can be characterized as linear (par. 0062).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Examiner, Art Unit 3762